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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,997	06/21/2007	Eric James Wall	CHM-022M	8939

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EXAMINER	
PRICE, NATHAN R	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,997	WALL ET AL.	
	Examiner	Art Unit	
	NATHAN R. PRICE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This office action is responsive to the amendment filed on May 12, 2009. As directed by the amendment: claims 3, 6-9, and 11 have been amended, no claims have been cancelled, and new claims 16 and 17 have been added. Thus, claims 1-17 are presently pending in this application, claims 12-15 being withdrawn from consideration. Applicant's amendments to the claims are sufficient to overcome the objections to the claims from the previous action.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-11, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McConnell-Montalvo et al. (US 6939330) in view of Woehr et al. (US 20030144627) and Hunn et al. (US 20040158207).

4. Regarding claims 1-5 and 16, McConnell-Montalvo et al. discloses an improved injection device for self-administering (capable of being self administered as defined by applicant in par. 0056, and claimed in claim 16; see Response to Arguments below) vaccine injections painlessly to a patient, comprising: a housing 70 (fig. 6) having a base portion (comprising elements 98 and widened distal end of housing 70, fig. 6 and 8); a needle 18 (fig. 8) positioned within the housing, the needle having an injection end

(sharp distal end, fig. 8), and being configured for extension to a position wherein the injection end extends through and beyond the base portion (see fig. 9); a reservoir for the vaccine (syringe barrel 10, fig. 8); and a means for liquid communication between the reservoir and the injection needle (needle 18 and reservoir 10 are connected in fluid communication, see fig. 8); a separable base (comprising elements 98, 102, and 106; fig. 8) associated with the base portion, a means for separably affixing the separable base with the base portion (interface between 100, 102) which is a mechanical securement (see fig. 8-9); the separable base is capable of being re-affixed to the base portion after separation (elements 102 are separated from the base during movement from position in fig. 8 to position in fig. 9, and in fig. 9 are reaffixed to the base at the top of space 100); **except** for the needle having an outside diameter greater than 0.20 mm and less than about 0.38 mm, an adhesive on a skin-facing surface thereof, an adhesive flap extending from a periphery of the separable base, the flap having an adhesive on a skin-facing surface thereof, whereby the flap provides securement of the separable base to the skin of the patient.

5. However, Woehr et al. teaches injection needles with diameters in this range (see table 1, page 5, which specifically mentions needle outer diameters of .3 mm, .33mm, and .35 mm). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the McConnell-Montalvo et al. apparatus such that the injection needle has an outside diameter greater than .10mm and less than about .38 mm, as taught by Woehr et al., for the purpose of providing a

needle of sufficiently sized diameter to require an appropriate application of strength for use (par. 0079, table 1).

6. Furthermore, Hunn et al. teaches an adhesive 2 (fig. 9; par. 0064) on a skin-facing surface comprising a flap that extends around the periphery of the base (see fig. 9). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the McConnell-Montalvo et al. apparatus such that it comprises an adhesive on a skin-facing surface thereof, an adhesive flap extending from a periphery of the separable base, the flap having an adhesive on a skin-facing surface thereof, whereby the flap provides securement of the separable base to the skin of the patient, as taught by Hunn et al., for the purpose of holding the apparatus in place at an injection site (par. 0064).

7. Regarding claims 6-11, McConnell-Montalvo et al. discloses the apparatus as claimed except for the means for separably affixing comprises engagements in the opposed surface of the separable base; and engaging members extending from the base portion of the housing; wherein the engaging members have a first position associated with the engagement wherein the removable base is secured to the housing, and a second position associated with the engagement wherein the removable base is not secured to the housing; the removable base has a slot in the opposed surface, wherein the engaging member has a latch whereby the latch engages the slot in its first position, thereby securing the separable base to the housing, and wherein the engaging member can be biased to the second position wherein the latch is not engaged with the slot, thereby unsecuring the separable base to the housing; the engaging member has a

button affixed thereto configured to accept a biasing force from outside the housing (preferably, through an opening within the housing), which biases the latch of the engaging member to its second, unsecured position; a means for retracting the injection needle whereby the injection end of the needle is retracted from its extended position to a position within the housing; the retracting means comprises a means for moving a needle insertion securement from a first position wherein the needle is secured in its extended position, to a second position wherein the needle is not secured in its extended position, and a needle retraction means for biasing the needle toward a position within the housing, whereby when the needle is not secured in its extended position, the needle is retracted to its housing position, wherein the injection end of the needle is positioned within the housing; and the engaging member can not be biased to its second position unless the needle is at its housing position, thereby preventing the injection end of the needle from being extended beyond the base portion of the housing when the separable base is removed from the housing.

8. However, Hunn et al. teaches the means for separably affixing comprises engagements 1a (fig. 11-12) in the opposed surface of the separable base; and engaging members 6c (fig. 11-12) extending from the base portion of the housing; wherein the engaging members have a first position associated with the engagement wherein the removable base is secured to the housing (see fig. 11), and a second position associated with the engagement wherein the removable base is not secured to the housing (see fig. 12); the removable base has a slot in the opposed surface, wherein the engaging member has a latch whereby the latch engages the slot in its first

position (see fig. 11 and 12; element 6c is formed as a latch that engages a slot in element 1a), thereby securing the separable base to the housing (shown in fig. 11), and wherein the engaging member can be biased to the second position wherein the latch is not engaged with the slot, thereby unsecuring the separable base to the housing (par. 0067; fig. 11-12); the engaging member has a button 6b (fig. 11-12) affixed thereto configured to accept a biasing force from outside the housing (par. 0067, fig. 11-12), which biases the latch of the engaging member to its second, unsecured position (par. 0067; fig. 11-12); a means for retracting (comprising elements 22, 23, and 25, fig. 10-12) the injection needle whereby the injection end of the needle is retracted from its extended position (shown in fig. 10) to a position within the housing (shown in fig. 11-12); the retracting means comprises a means 25 (fig. 10-12) for moving a needle insertion securement 23 (fig. 10-12) from a first position wherein the needle is secured in its extended position, to a second position wherein the needle is not secured in its extended position (par. 0074), and a needle retraction means 22 (fig. 10-12) for biasing the needle toward a position within the housing, whereby when the needle is not secured in its extended position, the needle is retracted to its housing position, wherein the injection end of the needle is positioned within the housing (see fig. 10-12); and the engaging member (as best understood, the engaging member referred to by applicant here is assumed to be the same as that in claim 6) can not be biased to its second position unless the needle is at its housing position (see fig. 10; depressing 6b when the needle is in this extended position would not be possible because of the presence of element 27 between the tabs 6b), thereby preventing the injection end of the needle

from being extended beyond the base portion of the housing when the separable base is removed from the housing (par. 0018).

9. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the McConnell-Montalvo et al. apparatus such that the means for separably affixing comprises engagements in the opposed surface of the separable base; and engaging members extending from the base portion of the housing; wherein the engaging members have a first position associated with the engagement wherein the removable base is secured to the housing, and a second position associated with the engagement wherein the removable base is not secured to the housing; the removable base has a slot in the opposed surface, wherein the engaging member has a latch whereby the latch engages the slot in its first position, thereby securing the separable base to the housing, and wherein the engaging member can be biased to the second position wherein the latch is not engaged with the slot, thereby unsecuring the separable base to the housing; the engaging member has a button affixed thereto configured to accept a biasing force from outside the housing (preferably, through an opening within the housing), which biases the latch of the engaging member to its second, unsecured position; a means for retracting the injection needle whereby the injection end of the needle is retracted from its extended position to a position within the housing; the retracting means comprises a means for moving a needle insertion securement from a first position wherein the needle is secured in its extended position, to a second position wherein the needle is not secured in its extended position, and a needle retraction means for biasing the needle toward a

position within the housing, whereby when the needle is not secured in its extended position, the needle is retracted to its housing position, wherein the injection end of the needle is positioned within the housing; and the engaging member can not be biased to its second position unless the needle is at its housing position, thereby preventing the injection end of the needle from being extended beyond the base portion of the housing when the separable base is removed from the housing, as taught by Hunn et al., for the purpose of preventing unintentional user injury (par. 0018).

10. Regarding claim 17, McConnell-Montalvo discloses the apparatus as claimed except for the volumetric flow rate of about 0.5 µL/s to about 20 µL/s. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to deliver medicament within the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

Response to Arguments

11. Applicant's arguments filed May 12, 2009 have been fully considered but they are not persuasive.

12. Applicant argues on page 7 of the Remarks that McConnell-Montalvo fails to disclose “self-administering” as defined by applicant in par. 0056 of the specification. However, the recitation “self administering” in claim 1 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the

preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

13. Applicant has defined "self administering" in the specification as follows: "as used herein, unless specified otherwise, the term 'self-administering' describes the ability of the device of the present invention to be held or to hold itself in a position attached to the skin of a patient by a securement means, without requiring a medical technician, the patient, or other person, to hold the device, during the time that an injectable liquid composition contained within the device is injected into the patient through the injection needle" (par. 0056). Applicant's new claim 16 also addresses this limitation. Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Examiner maintains that the limitation "self-administering" is a functional intended use limitation, and notes that any apparatus with a needle, if inserted at an injection site, is technically held in place as defined, since if released it would stay in place on the subject, and it must instead be manually removed by the person administering the injection.

14. Applicant argues on pages 7-8 of the Remarks, that Miskinyar fails to disclose a device for "painless intramuscular injection". First, the recitation "painless intramuscular injection" which is found in the preamble has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not

accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, the functional limitation "painless" may be interpreted very broadly, as pain threshold varies from one individual to another, from one species to another, and from one injection site to another. A recitation of the intended use of the claimed invention (administering a “painless” injection) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Examiner maintains that the McConnell-Montalvo apparatus is capable of administering a painless injection, especially to a subject or injection location with a high pain threshold.

15. Applicant argues on page 8 of the Remarks that McConnell–Montalvo fails to disclose a “separable” base which can be “reaffixed”. Once again, Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Examiner maintains that the base of McConnell-Montalvo is *capable* of being separated and reattached to the apparatus.

16. Applicant argues on pages 8-11 that Woehr et al. does not describe the use of any particular needle size or address the problem of pain caused by the use of larger-diameter sized needles during intramuscular needle insertion, that there is no rational basis to combine the teachings, and the rejection employs hindsight to combine specifically selected features from the teachings of the references. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Examiner maintains that Woehr et al. teaches ranges of commonly used needle diameters, including those claimed, from which Woehr indicates one of ordinary skill in the art at the time the invention was made would know to select based on desired push and pull strengths required for injection (see par. 0079, 0080, and Table 1). Regarding Applicant's

remarks in reference, once again, to the limitations involving "painless" injection, see arguments above.

17. Applicant argues on pages 9-10 of the Remarks that McConnell-Montalvo makes no disclosure or suggestion that the device is to be attached to the skin. See arguments in paragraph 12 above. Applicant further argues that Examiner provides no rationale basis to combine the teachings of McConnell-Montalvo and Hunn. However, Examiner notes rationale cited in par. 6 and 9 above (present in previous rejection).

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./
Examiner, Art Unit 3763

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